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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,981	06/05/2000	Jeffrey M. MacDonald	113918.201	8826

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EXAMINER
DEAK, LESLIE R

ART UNIT	PAPER NUMBER
3762	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

PR

Office Action Summary	Application No. 09/586,981	Applicant(s) MACDONALD ET AL.	
	Examiner Leslie R. Deak	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *30-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-29 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 8-13, 18, 21, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,015,585 to Robinson. Robinson discloses a bioreactor with a housing 14, nutrient inlets 11 and 21, nutrient outlets 12 and 22 that allow nutrient solutions to pass therethrough, an array of coaxial semipermeable fibers 34, with compartments defined within the innermost fiber (20), between the innermost fiber and the outermost fiber (30), and outside the outermost fiber (10). See FIGS 1, 2, column 2, lines 55-65, column 3, and column 6, lines 15-25. The nutrient solutions serve as an extracellular matrix by providing nutrients required for cell homeostasis, and may contain oxygen (see column 2, lines 57-63). The nutrient solution passes through the

porous hollow fibers allowing the nutrients to mix with murine hybridoma cells (which are eukaryotic cells) in section 30. Robinson further discloses that the fibers may be made of polysulfone and other polymers and the space between the fibers is 0.2 millimeters (column 4, lines 60-65, column 3, lines 50-55). The outermost chamber 10 is fed by its own inlet port 11 and outlet port 12 (column 3, lines 60-63). Cell chamber 30 is fed by a cell inlet port 31 and cell outlet port 32 (column 6, lines 16-25). The innermost chamber 20, within the intracapillary hollow fiber 24, is fed by nutrient inlet 21 and outlet 22 (column 3, lines 30-40). Potting compounds 13 and 33 and module shell 14 separate and isolate and separate the flow entering through different ports, separating that fluid from the remaining volume of the bioreactor and distributing it to the proper area of the bioreactor (column 3, lines 38-44, 56-61, 64-67). The bioreactor illustrated in FIG 1 has a hollow tube 17cm long and a pore size of 0.2 microns, falling within the range claimed by applicant.

With regard to applicant's claim drawn to the method of sterilization of the bioreactor, such a limitation amounts to a recitation of the intended use of the device, and does not patentably distinguish from the prior art.

Claim Rejections - 35 USC § 103

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5-7, 14, 19-20, 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,015,585 to Robinson. Robinson discloses the apparatus as claimed with the exception of using liver cells, the number of cells in the bioreactor, and the pore size of the hollow fibers. Robinson does, however, disclose that the bioreactor is designed for use in growing human cells, of which liver cells are an obvious subset (see column 4, lines 14-23). Therefore, since Robinson discloses the use of human cells in his bioreactor, it would have been obvious to one of ordinary skill in the art at the time of invention to use liver cells, since liver cells are a type of human cell. Furthermore, Robinson discloses that his bioreactor comprises 5-6 x 10^8 cells, and a pore size of 0.2 microns, further disclosing that particular parameters of the bioreactor may be modified depending on the desired cell culture operation. It would have been obvious to one having ordinary skill in the art at the time of invention to vary the number of cells used in the bioreactor and to vary the pore size of the hollow fibers, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05.

With regard to applicant's claim that the inlets and outlets of the bioreactor are located on a first end of the housing, such a recitation amounts to a rearrangement of parts of the device. Mere rearrangement of the working parts of a device involves only routine skill in the art. See MPEP 2144.04.

With regard to applicant's claim drawn to a bioreactor with two subunits, the second subunit is a mere duplication of the previously claimed bioreactor. It would have been obvious to one of ordinary skill in the art at the time of invention to add a second bioreactor unit to the previously disclosed apparatus since it has been haled that the mere duplication of the essential working parts of a device involves only routine skill in the art. See MPEP 2144.04.

7. Claims 15, 22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,015,585 to Robinson in view of US 6,218,182 to Naughton et al. Robinson discloses the apparatus as claimed but does not disclose the method of treating a patient. Naughton discloses the process of passing plasma passing patient plasma through the bioreactor and returning it to the patient wherein the plasma is modified in the bioreactor (see column 7, lines 1-10). The method is used such that the artificial liver cells in the bioreactor perform filtering functions on the patient plasma, acting as an artificial liver. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the hollow fiber bioreactor disclosed by Robinson in the plasma treatment method disclosed by Naughton in order to treat patient plasma with

cells grown in the bioreactor. Similarly, it would have been obvious to pass the patient plasma through 2 subunits of a bioreactor since mere duplication of the steps of the method would have been obvious to one of ordinary skill in the art at the time of invention. See MPEP 2144.04.

With regard to applicant's claim drawn to a microfiber, Naughton discloses a bioreactor that may comprise nylon fibers with a diameter of 90 micrometers in order to provide a biodegradable mesh for cell implantation in the patient's body (see column 8, lines 29-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add microfibers to the hollow-fiber bioreactor disclosed by Robinson in order to allow for implantation of the grown cells into the patient.

8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,015,585 to Robinson in view of US 6,218,182 to Naughton et al in view of US 5,510,262 to Stephanopoulis et al. Robinson and Naughton disclose the apparatus as claimed with the exception of aeration and perfluorocarbon coating on the microfiber growth area within the bioreactor. Stephanopoulis discloses a hollow fiber cell culture device that uses a growth medium 30 in a medium reservoir 32. The medium is aerated to increase oxygen content and promote growth (see column 8, lines 20-37). Similarly, the medium can be treated with perfluorocarbon in order to increase the oxygen solubility in the growth medium, improving cell growth (see column 9, lines 20-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add aeration and a perfluorocarbon treatment to a portion of the cell

incubation area of the bioreactor disclosed by Robinson and Naughton in order to increase oxygen solubility and cell growth, as taught by Stephanopoulis.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. WO 00/75275 A2 MacDonald et al

i. International publication of applicant's invention

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd
April 4, 2003

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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